UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: February 8, 2023

SUBJECT: Efficacy Review for Neogen® Viroxide Super™,
EPA Reg. No. 66171-106
Action Code Case: 00398189
E-submission No. 80707

FROM: Luisa C. Samalot-Freire
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: January 27, 2023

THRU: Sophie Nguyen
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: February 8, 2023

TO: Stacey Grigsby / Marcel Howard, PM 34
Regulatory Management Branch II
Antimicrobials Division (7510M)

APPLICANT: Preserve International

Formulation from the Label:

Active Ingredient(s)	% by wt.
Potassium peroxymonosulfate	22.41%
Sodium chloride	1.50%
Other Ingredients	76.09%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Dilutable Solid (Powder)

Submission type: Label Amendment

Currently registered efficacy claim(s): Cleaner and disinfectant (bactericide and virucide) for hard non-porous surfaces on industrial settings.

Requested action(s): Label amendment for a concentrated dilutable solid (powder) to be used as a disinfectant and virucide on hard non-porous surfaces

Documents considered in this review:

- Cover letter from applicant to EPA dated 10/5/2022
- Proposed label dated 10/5/2022
- Data Matrix (EPA Form 8570-35) dated 10/5/2022
- Twelve efficacy studies (MRIDs 52026301 through 52026312)
- Confidential Statement of Formula (EPA Form 8570-4) dated 11/25/2020
- Efficacy Review: Efficacy Review for Neogen Viroxide Super, EPA Reg. No. 66171-106, Case #: 00217008 – dated 1/6/2021

II. PROPOSED DIRECTIONS FOR USE

"**DIRECTIONS FOR USE**
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
READ THIS LABEL: Read this entire label and follow all use directions and precautions.
GENERAL INSTRUCTIONS
1. Remove all animals and feeds from premises, trucks or other vehicles, crates, or other enclosures.

2. Remove all litter droppings and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water. Visible solid must be removed from surfaces prior to disinfecting.

5. **To disinfect**, saturate visibly clean hard nonporous surfaces with a 1% use-dilution of this product [see dilution chart], surfaces should remain visibly wet for 10 minutes.

6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. Ventilate buildings, cars, boats, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.

8. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[this product] DILUTION CHART

To achieve the appropriate [this product] use-dilution concentration, fill the container with the volume of water and quantity of powder found in the following table:

Quantity of Water	**1% Dilution**
1 Quart	0.3 ounces
1 Gallon	1.3 ounces
10 Gallons	13.4 ounces
50 Gallons	66.8 ounces

One gallon of solution is sufficient to treat 135 sq. ft.
[This powder formulation is easily diluted for use in manual or machine operations.]

POULTRY PRODUCTION AND RATITE PRODUCTION

[**For Use in**] **HATCHERIES:** [This product] as a 1.0% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes. Visible soil must be removed from surfaces prior to disinfecting. Saturate surfaces with a 1.0% solution of [this product] with a cloth, mop, sponge, or mechanical spray, and should remain visibly wet for10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

[For Use in] BROILER/BREEDER HOUSES: Follow **General Instructions** to remove poultry and preclean area to be treated. Visible soil must be removed from surfaces prior to disinfecting. Spray floors and walls with [this product] as a 1% solution. Thoroughly wash waterers and feeders with a 1% solution of [this product]. Surfaces should remain visibly wet for 10 minutes. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has been absorbed, set, or dried.

[For Use in] FOOD- or MEAT-PROCESSING PLANTS: Visible soil must be removed from surfaces prior to disinfecting. Spray [this product] as a 1% solution to disinfect and clean walls, ceilings, and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry.

SWINE PRODUCTION:

Follow **General Instructions** to remove swine and preclean area to be treated. Visible soil must be removed from surfaces prior to disinfecting. Use a 1% solution of [this product] cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of [this product] with a cloth, mop, sponge, or mechanical spray, surfaces should remain visibly wet for 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

EQUINE PRODUCTION

[BROAD SPECTRUM EQUINE FACILITY DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES AND EQUIPMENT]

GENERAL USE APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils, and instruments in veterinary practices, kennels, stables, catteries, etc.

USES: stables, horse boxes, box stalls, tack, equipment, and feed rooms: Follow **General Instructions** to remove animals from area to be treated. Visible soil must be removed from surfaces prior to disinfecting. Thoroughly clean and dry [dry clean] surfaces, then wash the area manually or with pressure washer with a 1% [product] solution, saturating surfaces and should remain visibly wet for 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

T**o Clean Blankets, Saddle Pads and Rugs**: Visible soil must be removed from surfaces prior to disinfecting. Using a 1% solution of [this product], shampoo by hand or spray lightly with a hand-sprayer remaining visibly wet for 10 minutes and leave to dry. Shake or vacuum to remove residue.

BOVINE PRODUCTION
Follow **General Instructions** to remove livestock and preclean area to be treated. Visible soil must be removed from surfaces prior to disinfecting. Use a 1%
solution of [this product] to clean and disinfect areas associated with bovine housing, stabling, hospital quarantine pens, feedlot facilities, and agricultural production equipment, such as trucks, waterproof footwear (such as rubber boots), and associated livestock equipment and instruments. Saturate hard, non-porous surfaces with a 1% solution of [this product] with a cloth, mop, sponge, or mechanical spray, surfaces should remain visibly wet for 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.
[COMPANION ANIMAL FACILITIES]
[APPLICATION INSTRUCTIONS: Use a 1% solution of [this product] as a “one step” cleaning and disinfecting procedure (Visible soil must be removed from surfaces prior to disinfecting) for all hard, non-porous surfaces, equipment, instruments, utensils, and cages [caging systems] within [or associated with] veterinary medical hospitals, animal infectious disease wards, quarantine areas, laboratory animal quarters, grooming and boarding facilities, kennels, catteries, and animal transportation vehicles. Saturate hard, non-porous surfaces with a 1% solution of [this product] with a cloth, mop, sponge, or mechanical spray, surfaces should remain visibly wet for 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]
[Do not immerse metal objects in [this product] for long periods. Once the specified contact time is reached, remove metal objects from the solution.]
[FACILITIES USED FOR TEMPORARY CONFINEMENT OF ANIMALS]
Use a 1% solution of [this product] to clean and disinfect inanimate hard, non-porous surfaces associated with facilities used for the temporary confinement of animals. Sites may include, but are not limited to, barns, sheds, stables, pens, cages, and associated access alleys or walkways. [This product] may also be used to clean and disinfect equipment related to the maintenance of animals housed at fairs, exhibitions, animal auction yards, animal show/boarding facilities, or other similar agricultural facilities designed for the temporary housing of animals.
To ensure that [this product] does not come into direct contact with animals, feed, or water, remove animals from treatment site and either remove or cover feed and water apparatus. Visible soil must be removed from surfaces prior to disinfecting. To ensure precise application on inanimate surfaces, [this product] may only be applied using hand-held sprayers, sponges, or other absorbent materials. Do not allow [this product] to pool on surfaces that may be within reach of animals. Do not allow [this product] to come into direct contact with people. Surfaces should remain visibly wet for 10 minutes. Allow [this product] to completely dry prior to housing animals, using equipment, or allowing people to contact treated sites.
[AQUACULTURE]
[This product] is intended to disinfect hard, non-porous inanimate environmental surfaces associated with aquaculture including vehicles, nets, boots, waders, dive suits, hoses, brushes, and other similar equipment. [This product] may also be used in foot dips. [This product] must not be applied directly to water.
[GREENHOUSES AND HORTICULTURE]
[[This product] is intended to disinfect hard, non-porous inanimate environmental surfaces such as: floors, walls, glasshouse structures, ventilation and other equipment, utensils, trays, and other containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. It is not intended to directly affect agricultural production and must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.]
[For surfaces and equipment
1. Sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove

loose dirt. Visible soil must be removed from surfaces prior to disinfecting.
2. Use a dilution of 1.3 oz. [this product] per gallon of clean water.

3. Apply solution with mop, sponge, or cloth to thoroughly wet all surfaces. Surfaces should remain visibly wet for 10 minutes.

4. Visible growth of algae or fungi may have to be scrubbed off following application.

5. Reapply as often as needed for control.]

[Pots, flats, trays: use a dilution of 1.3 oz. per gallon of clean water. Soak tools to ensure complete coverage.]
[Work areas: sweep and remove all plant debris. Use power sprayer to wash all surfaces to remove loose dirt, visible soil must be removed from surfaces prior to disinfecting Use a dilution of 1.3 oz. of [this product] per gallon of clean water.]."

III. STUDY SUMMARIES

1.	**MRID**	52026301	
Study Objective		Disinfectant – bactericidal	
Study Title		AOAC Use-Dilution Method	
Testing Lab; Lab Study ID		Accuratus Lab Services; A28810	
Experimental Start Date		11/19/2019	**Study Completion Date:** 11/21/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Escherichia coli* (ATCC 11229)	
Test Method		AOAC Use Dilution method Protocol No. NEO002050619.UD.3	
Application Method		Liquid (dilutable solid/powder)	
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super	
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908005 S110419-07	
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon prepared using 1.47 g test substance + 151.4 mL diluent. Diluent: 400 ppm AOAC Synthetic Hard water	
Soil load		5% Fetal Bovine Serum (FBS)	
Carrier type, # per lot		Stainless steel penicylinders; 10 carriers/lot	
Test conditions		Contact time: 10 minutes Temperature: 20±1°C (20.0°C) Relative humidity: N/A	
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate	
Incubation Conditions		48-54 hours (46.5 hours) at 35-37°C (36.0°C)	
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments or deviations noted	

2.	**MRID**	52026302		
Study Objective		Disinfectant – bactericidal		
Study Title		AOAC Use-Dilution Method		
Testing Lab; Lab Study ID		Accuratus Lab Services; A28811		
Experimental Start Date		11/20/2019	**Study Completion Date:**	11/22/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica subspecies enterica seroval Typhimurium* (ATCC 14028)		
Test Method		AOAC Use Dilution method Protocol No. NE0002050619.UD.4		
Application Method		Liquid (dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908005 S110419-07		
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon prepared using 1.47 g test substance + 151.4 mL diluent. Diluent: 400 ppm AOAC Synthetic Hard water		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		Stainless steel penicylinders; 10 carriers/lot		
Test conditions		Contact time: 10 minutes Temperature: 20±1°C (20.0°C) Relative humidity: N/A		
Neutralizer		Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate		
Incubation Conditions		48-54 hours (47.75 hours) at 35-37°C (36.0°C)		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments. Protocol Deviations: The protocol states that the acceptance criteria for the carrier population control is 4.0-5.0 Log_{10}. In testing, the carrier population control was 5.09 Log_{10}, which exceeded the upper limit and therefore did not meet the acceptance criteria. However, the test substance demonstrated passing efficacy results and therefore the results are deemed valid. This deviation has no impact on the overall intent of the protocol as both batches of test substance demonstrated passing efficacy results.		

3	**MRID**	52026303		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Accuratus Lab Services; A28863		
Experimental Start Date		11/25/2019	**Study Completion Date:**	12/2/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Avian Influenza A (H5N1) virus, Strain VNHSN1 -PR8/CDC-RG, CDC #200671 9965		

		Obtained from the Centers for Disease Control and Prevention (CDC), Atlanta, GA
Indicator Cell Culture		MDCK cells (ATCC CCL-34)
Test Method		ASTM E1053-11 Protocol # NEO002050719.AFLU
Application Method		Liquid (Dilutable solid/powder)
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water
Soil load		5% Fetal Bovine Serum
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200 µL of inoculum
Test conditions		Contact time: 10 minutes Temperature: 21.0°C Relative humidity: Not reported
Neutralizer		Sephadex LH-20 gel
Incubation Conditions		7 days at 36-38°C with 5-7% CO_2 (6.0-6.1% CO_2)
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendment or deviations noted on the report.

4.	**MRID**	52026304		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest; A28899		
Experimental Start Date		12/6/2019	**Study Completion Date:**	12/27/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Infectious Laryngotracheitis virus, Strain LT-IVAX (Modified live vaccine), Obtained from Poultry Health and Specialties, St. Cloud, MN		
Indicator Cell Culture		CEK cells (chicken embryo kidney) originally obtained from Charles River.		
Test Method		ASTM E1053-11 Protocol # NEO002052319.ILGT		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908003		
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water		

Soil load	5% Fetal Bovine Serum
Carrier type, # per lot	100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200 µL of inoculum
Test conditions	Contact time: 10 minutes Temperature: 20.0°C Relative humidity: Not reported
Neutralizer	Sephadex LH-20 gel
Incubation Conditions	7 days at 36-38°C (37.0°C) with 5-7% CO_2 (6.0% CO_2)
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol amendment: To correct a typographical error on page 2 of the protocol attachment, this protocol is amended to replace lot "RDB1908002" with "RDB1908003". No protocol deviations noted on the report. Report notes: The initial assay performed on December 6, 2019, was repeated on December 20, 2019, in order to recover at least 4.8 log_{10} of infectivity per carrier from the dried virus control film, as required for a valid study.

5.	**MRID**	52026305		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Accuratus Lab Services; A29066		
Experimental Start Date		1/20/2020	**Study Completion Date:**	1/13/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Infectious Bursal Disease virus – *strain not identified* (obtained from Solvay Animal Health)		
Indicator Cell Culture		Vero cells (ATCC CCL-81)		
Test Method		ASTM E1053-11 Protocol # NEO002050719.18D		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002		
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200 µL of inoculum		
Test conditions		Contact time: 10 minutes Temperature: 20.0°C Relative humidity: 50%		
Neutralizer		Sephadex LH-20 gel		
Incubation Conditions		7 days at 36-38°C (37.0°C) with 5-7% CO_2 (6.0% CO_2)		
Reviewer comments		Protocol amendments:		

(i.e. protocol deviations and amendments, retesting, control failures, etc.)	1. Per sponsor request, Lot RDB1908003 is updated to RDB1908002 in the protocol and the protocol attachment, for use in testing. 2. Due to a typographical error, the check box selection for the section "Protocol Attachments" on page 10 of the protocol was not completed. A protocol attachment was included by the sponsor; therefore, this section will be indicated as yes. No protocol deviations noted in the report.

6.	**MRID**	52026306		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest; A28887		
Experimental Start Date		12/16/2019	**Study Completion Date:**	1/10/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Avian Infectious Bronchitis virus / Beaudette IB42 strain - obtained from Solvay Animal Health		
Indicator Cell Culture		Fertilized chicken eggs – obtained from Charles River		
Test Method		ASTM E1053-11 Protocol # NEO002050719.IBV		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002		
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200 µL of inoculum		
Test conditions		Contact time: 10 minutes Temperature: 20.0°C Relative humidity: 50%		
Neutralizer		Sephadex LH-20 gel		
Incubation Conditions		The eggs were incubated at 34-38°C (34.0-36.0°C) in a relative humidity of 40-80% (43-65%) for four days.		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol amendments: This protocol is amended to correct a typographical error in section a, on page 1 of the protocol attachment. "Cytotoxicity" is corrected to "toxicity" and "cytotoxic" is corrected to "toxic". No protocol deviations noted in the report. Report notes:		

	The initial assay performed on December 16, 2019, was repeated on January 6,2020, to recover at least 4.8 log_{10} of infectivity per carrier from the dried virus control film and to demonstrate a >3 log_{10} reduction in titer beyond the level of neutralization, as required for a valid study. In addition to the invalid dried virus control, the test results from the December 16, 2019, assay is also questionable. Due to the way in which dilutions (10-fold serial) are performed for this test, the data generated from testing on December 16, 2019 does not scientifically make sense and was determined to be scientifically unreasonable, further indicating that a repeat test was necessary. The testing performed on January 6, 2020, demonstrated results that are expected, due to the way in which serial dilutions are performed.

7.	**MRID**	52026307		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus		
Testing Lab; Lab Study ID		Accuratus Lab Services; A28897		
Experimental Start Date		12/4/2019	**Study Completion Date:**	12/11/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus – NADL strain (ATCC VR-1422)		
Indicator Cell Culture		Cultures of bovine turbinate (BT) cells – ATCC: CRL-1390		
Test Method		ASTM E1053-11 Protocol # NEO002050719.BVD		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002		
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water		
Soil load		5% Horse Serum		
Carrier type, # per lot		100 mm glass petri dishes; 2 carrier per lot / carriers inoculated with 200 µL of inoculum		
Test conditions		Contact time: 10 minutes Temperature: 20.0°C Relative humidity: Not reported		
Neutralizer		Sephadex LH-20 gel		
Incubation Conditions		7 days at 36-38°C (37.0°C) with 5-7% CO_2 (6.0% CO_2)		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendment or deviations noted in the report.		

8.	**MRID**	52026308
Study Objective		Disinfectant – virucide
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Testing Lab; Lab Study ID		Accuratus Lab Services; A29067
Experimental Start Date		1/20/2020 **Study Completion Date:** 1/27/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Porcine Respiratory & Reproductive Syndrome (PRRS) virus, NVSL Strain, Obtained from the University of Kentucky
Indicator Cell Culture		MARC-145 cells, obtained from the National Veterinary Services Laboratory, Ames, IA
Test Method		ASTM E1053-11 Protocol # NEO002050719.PRRS
Application Method		Liquid (Dilutable solid/powder)
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water
Soil load		5% Fetal Bovine Serum
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200 µL of inoculum
Test conditions		Contact time: 10 minutes Temperature: 20.0°C Relative humidity: 50%
Neutralizer		Sephadex LH-20 gel
Incubation Conditions		7 days at 36-38°C (37.0°C) with 5-7% CO_2 (5.5-6.0% CO_2)
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol amendments: 1. Per sponsor request, Lot RD81908003 wass updated to RD81908002 in the protocol and the protocol attachment, for use in testing. 2. Due to a typographical error, the sponsor dated the protocol for approval on May 10, 2019, but did not sign the protocol on this date. The protocol is amended to indicate, per sponsor email dated January 31,2020, the sponsor approved the protocol prior to testing and acknowledges the approval signature was to occur on the approval date of May 10,2019. No protocol deviations noted in the report.

9.	**MRID**	52026309
Study Objective		Disinfectant – virucide
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Testing Lab; Lab Study ID		Accuratus Lab Services; A29087		
Experimental Start Date		1/20/2020	**Study Completion Date:**	1/27/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Pseudorabies virus, ATCC VR-135, Strain Aujeszky		
Indicator Cell Culture		CRFK (feline kidney) cells – ATCC: CCL-94		
Test Method		ASTM E1053-11 Protocol # NEO002050719.PSRV		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002		
	Preparation	Tested concentration: LCL Tested Dilution: 1.3 oz/gallon dilution defined as 1.3 oz test substance + 1 gallon diluent – prepared as 1.00 g product + 102.7 mL diluent Diluent: 400 ppm AOAC Hard Water		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200 µL of inoculum		
Test conditions		Contact time: 10 minutes Temperature: 20.0°C Relative humidity: 40%		
Neutralizer		Sephadex LH-20 gel		
Incubation Conditions		7 days at 36-38°C (37.0°C) with 5-7% CO_2 (5.5-6.0% CO_2)		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments or deviations noted in the report.		

10.	**MRID**	52026310		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc. / 593-162		
Experimental Start Date		11/20/2019	**Study Completion Date:**	11/27/2019
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Newcastle Disease Virus / Strain: LaSota – Source: Charles River Laboratories		
Indicator Cell Culture		Vero cells – ATCC: CCL-81		
Test Method		ASTM E1053-11 Protocol # 593.1.11.12.19		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002		
	Preparation	Tested concentration: LCL Tested Dilution: 1% (1 part test substance + 99 parts diluent) – prepared as 1 g test substance + 99 mL 394 ppm AOAC hard water (equivalent to 1:100 dilution)		

		Diluent: 400 ppm AOAC Hard Water ± 2.9% ppm
Soil load		5% Serum
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 0.4 mL of inoculum
Test conditions		Contact time: 10 minutes Temperature: 21°C Relative humidity: 31-32%
Neutralizer		Sephadex LH-20
Incubation Conditions		7 days at 36 ± 2°C with 5 ± 3% CO_2
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol amendments or deviations noted in the report.

11.	**MRID**	52026311		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal efficacy of a disinfectant “Neogen Viroxide Super” for use on inanimate environmental surfaces on African Swine Fever Virus		
Testing Lab; Lab Study ID		IRTA-CReSA Campus Universitat Autònoma de Barcelona 08193 Bellaterra (Cerdanyola del Vallès), Barcelona. Spain / SA-9378-19		
Experimental Start Date		10/20/2020	**Study Completion Date:**	6/29/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		African Swine Fever Virus / Strain: Ba71V		
Indicator Cell Culture		Vero cells – ATCC: CCL-81		
Test Method		ASTM E1053-11 Reference No.: GLP4		
Application Method		Liquid (Dilutable solid/powder)		
Test Substance Preparation	**Name/ID**	Neogen Viroxide Super		
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002 RDB1908003		
	Preparation	Tested concentration: LCL Tested Dilution: 1:200 – prepared as 5g test substance + 1000 mL diluent. 1:400 – prepared as 2.5g test substance + 1000 mL diluent. Diluent: 400 ppm AOAC Hard Water ± 2.9% ppm		
Soil load		5% Fetal Bovine Serum		
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200µL of inoculum		
Test conditions		Contact time: 10 minutes Temperature: Room Temperature (24.4°C ± 0.7°C) Relative humidity: Not reported		
Neutralizer		Sephadex LH-20		
Incubation Conditions		5 days at 37°C with 5% CO_2		
Reviewer comments		Protocol Amendments:		

(i.e. protocol deviations and amendments, retesting, control failures, etc.)	1. As presented on page 34 of report: The use of the centrifuge will obtain more homogeneous results in all the filtrations through individual Sephadex columns since ll the syringes will be equally treated. The use of the centrifuge will be less aggressive than the use of manual pressure performed with the syringe-plunger. 2. As presented on page 35 of report: Performing the cytotoxicity assay *prior* to the assays assessing the effect of the disinfectant on virus-films, instead of performing it *concurrently* with them, will speed up all the process, since the amount of work in such way is more affordable than performing all the tests concurrently. 3. As presented on page 36 of report: The ASFV-strain used in the present study is Ba71V (not Georgia2007) and such is adapted to growth on Vero cell culture. Such ASFV-strain is no longer infective on primary porcine alveolar macrophages (as it is the case for Georgia 2007). 4. As presented on page 37 of report: The disinfectant to test is presented in powder. it is not liquid. Hence, we must use grams instead of milliliters. 5. As presented on page 38 of report: The ASFV-strain used in the present study is Ba71V, a strain adapted to growth on Vero cell culture. Such ASFV-strain is no longer infective on primary porcine alveolar macrophages, and so, any SOP related to the obtention, and handling of PAMs will not be used. 6. As presented on page 39 of report: Correction as Patrice Fields does not work for Neogen Corporation anymore.

12.	**MRID**	52026312		
Study Objective		Disinfectant – virucide		
Study Title		Virucidal efficacy of a disinfectant “Neogen Viroxide Super” for use on inanimate environmental surfaces on African Swine Fever Virus		
Testing Lab; Lab Study ID		IRTA-CReSA Campus Universitat Autònoma de Barcelona 08193 Bellaterra (Cerdanyola del Vallès), Barcelona. Spain / SA-9277-19		
Experimental Start Date		3/24/2021	**Study Completion Date:**	4/28/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		African Swine Fever Virus / Strain: Georgia2007		
Indicator Cell Culture		Primary PAMs of swine origin were used (ASFV strain Georgia 2007 is not able to grow in established or immortalized cell-lines) as cell line in the infectivity assays		
Test Method		ASTM E1053-11 Reference No.: GLP3		
Application Method		Liquid (Dilutable solid/powder)		

Test Substance Preparation	**Name/ID**	Neogen Viroxide Super
	Lots **☐ 1 ☒ 2 ☐ 3**	RDB1908001 RDB1908002 RDB1908003
	Preparation	Tested concentration: LCL Tested Dilution: 1:200 – prepared as 5g test substance + 1000 mL diluent. 1:400 – prepared as 2.5g test substance + 1000 mL diluent. Diluent: 400 ppm AOAC Hard Water ± 2.9% ppm
Soil load		5% Fetal Bovine Serum
Carrier type, # per lot		100 mm glass petri dishes; 1 carrier per lot / carriers inoculated with 200µL of inoculum
Test conditions		Contact time: 10 minutes Temperature: Room Temperature (22°C ± 2°C) Relative humidity: Not reported
Neutralizer		Sephadex LH-20
Incubation Conditions		5 days at 37°C with 5% CO_2
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. As presented on page 35 of report: The use of the centrifuge will obtain more homogeneous results in all the filtrations through individual Sephadex columns since ll the syringes will be equally treated. The use of the centrifuge will be less aggressive than the use of manual pressure performed with the syringe-plunger. 2. As presented on page 36 of report: Performing the cytotoxicity assay *prior* to the assays assessing the effect of the disinfectant on virus-films, instead of performing it *concurrently* with them, will speed up all the process, since the amount of work in such way is more affordable than performing all the tests concurrently. 3. As presented on page 37 of report: to update test medium due to availability. 4. As presented on page 38 of report: The disinfectant to test is presented in powder, it is not liquid. Hence, we must use grams instead of milliliters. 5. As presented on page 39 of report: Correction as Patrice Fields does not work for Neogen Corporation anymore.

IV. **STUDY RESULTS**

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Average log_{10} CFU/Carrier
		RDB1908005	S110419-07	
10-minute contact time, dilutable powder (1.3 oz./gallon) in 400 ppm AOAC Synthetic Hard Water				
52026301	*Escherichia coli* (ATCC 11229)	0/10	0/10	4.75
52026302	*Salmonella enterica* Subspecies *enterica* serovar Typhimurium (ATCC 14028)	0/10	0/10	5.09

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			RDB1908001	RDB1908002	
10-minute contact time, dilutable powder (1.3 oz./gallon, unless otherwise noted[#]) in 400 ppm AOAC hard water, 5% soil load					
52026303	Avian Influenza A (H5N1) virus, Strain VNHSN1 - PR8/CDC-RG, CDC #200671 9965 Obtained from the Centers for Disease Control and Prevention (CDC), Atlanta, GA	10^{-1} to 10^{-7} dilution	Complete inactivation	Complete inactivation	6.55
		Log_{10} $TCID_{50}$/carrier	≤0.80	≤0.80	
		Log Reduction	≥5.75	≥5.75	
52026304	Infectious Laryngotracheitis virus, Strain LT-IVAX (Modified live vaccine), Obtained from Poultry Health and Specialties, St. Cloud, MN	**Description**	**Results**		**Dried Virus Control (Log_{10} $TCID_{50}$/carrier)**
			RDB1908001	**RDB1908003**	
		10^{-1} to 10^{-6} dilution	Complete inactivation	Complete inactivation	5.05
		Log_{10} $TCID_{50}$/carrier	≤0.80	≤0.80	
		Log Reduction	≥4.25	≥4.25	
52026305	Infectious Bursal Disease virus (obtained from Solvay Animal Health)	10^{-1} to 10^{-7} dilution	Complete inactivation	Complete inactivation	5.55
		Log_{10} $TCID_{50}$/carrier	≤0.80	≤0.80	
		Log Reduction	≥4.75	≥4.75	

MRID	Organism	Description	Results				Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			RDB1908001		RDB1908002		
10-minute contact time, dilutable powder (1.3 oz./gallon, unless otherwise noted[#]) in 400 ppm AOAC hard water, 5% soil load							
52026306	Avian Infectious Bronchitis virus, Strain Beaudette 1B42, Obtained from Solvay Animal Health	10^{-1} to 10^{-6} dilution	Complete inactivation		Complete inactivation		5.63
		Log_{10} $TCID_{50}$/carrier	≤0.80		≤0.80		
		Log_{10} $TCID_{50}$/0.1mL	≤0.50		≤0.50		
		Log Reduction per 0.1mL & per carrier	≥4.58		≥4.33		
52026307	Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus / NADL strain (ATCC VR-1422)	Replicate	1	2	1	2	5.37
		10^{-1} to 10^{-4} dilution	Complete inactivation	Complete inactivation	Complete inactivation	Complete inactivation	
		Average Log_{10} $TCID_{50}$/carrier	≤0.80		≤0.80		
		Average Log Reduction	≥4.57		≥4.57		
52026308	Porcine Respiratory & Reproductive Syndrome (PRRS) virus, NVSL Strain, Obtained from the University of Kentucky	10^{-1} to 10^{-7} dilution	Complete inactivation		Complete inactivation		5.55
		Log_{10} $TCID_{50}$/carrier	≤0.80		≤0.80		
		Log Reduction	≥4.75		≥4.75		
52026309	Pseudorabies virus, ATCC VR-135, Strain Aujeszky	10^{-1} to 10^{-7} dilution	Complete inactivation		Complete inactivation		7.30
		Log_{10} $TCID_{50}$/carrier	≤0.80		≤0.80		
		Log Reduction	≥6.50		≥6.50		
52026310 [#](1g test substance + 99mL water)	Newcastle Disease Virus / Strain: LaSota / Source: Charles River Laboratories	10^{-2} dilution	T/4		T/4		6.35
		10^{-3} to 10^{-7} dilution	0/4		0/4		
		Log_{10} $TCID_{50}$/carrier	≤2.10		≤2.10		
		Log Reduction	≥4.25		≥4.25		

MRID	Organism	Description	Results		
			RDB1908001	**RDB1908002**	**RDB1908003**
10-minute contact time, dilutable powder, 5% soil load*					
52026311	African Swine Fever Virus, Strain Ba71V	1:200 dilution* *in 400 ppm AOAC hard water^*			
		10^{-1} to 10^{-8} dilution	0/8	0/8	0/8
		Log_{10} $TCID_{50}$	≤1.5	≤1.5	≤1.5
		Log Reduction	≥4.75	≥4.75	≥4.67
		ASFV-Control **(Log_{10} $TCID_{50}$)**	6.25 ± 0.11	6.25 ± 0.11	6.17 ± 0.17
		1:400 dilution* *in 400 ppm AOAC hard water^*			
		10^{-1} to 10^{-8} dilution	0/18	0/18	0/18
		Log_{10} $TCID_{50}$	≤1.5	≤1.5	≤1.5
		Log Reduction	≥4.25	≥4.25	≥4.00
		ASFV-Control **(Log_{10} $TCID_{50}$)**	5.75 ± 0.11	5.75 ± 0.11	5.50 ± 0.00

^data for 250 ppm AOAC hard water were not reviewed. At 250 ppm AOAC hard water, this does not meet the required calcium carbonate ppm permitted for the AOAC hard water option for testing.

MRID	Organism	Description	Results		
			RDB1908001	**RDB1908002**	**RDB1908003**
10-minute contact time, dilutable powder in 400 ppm AOAC hard water^, 5% soil load*					
52026312	African Swine Fever Virus, Strain Georgia 2007	1:200 dilution*			
		10^{-1} to 10^{-8} dilution	0/18	0/18	0/18
		Log_{10} $TCID_{50}$	≤1.5	≤1.5	≤1.5
		Log Reduction	≥3.81	≥3.81	≥4.56
		ASFV-Control **(Log_{10} $TCID_{50}$)**	5.31 ± 0.10	5.31 ± 0.10	6.06 ± 0.13
		1:400 dilution*			
		10^{-1} to 10^{-8} dilution	0/18	0/18	0/18
		Log_{10} $TCID_{50}$	≤1.5	≤1.5	≤1.5
		Log Reduction	≥3.81	≥3.81	≥4.56
		ASFV-Control **(Log_{10} $TCID_{50}$)**	5.31 ± 0.10	5.31 ± 0.10	6.06 ± 0.13

^same as above

V. **STUDY CONCLUSIONS**

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil Load	Diluent	Organism(s)	Data support tested conditions?
52026301	Disinfectant, bactericidal	Hard, non-porous surfaces	Dilutable powder; 1.3 oz/gallon	10 minutes	5% soil load	400 ppm AOAC Hard water	• *Escherichia coli* (ATCC 11229)	**Yes**
52026302	Disinfectant, bactericidal						• *Salmonella enterica subspecies enterica serovar* Typhimurium (ATCC 14028)	**Yes**
52026303	Disinfectant, virucidal						• Avian Influenza A (H5N1) virus, Strain VNHSN1 - PR8/CDC-RG, CDC #200671 9965 Obtained from the Centers for Disease Control and Prevention (CDC), Atlanta, GA	**Yes**
52026304							• Infectious Laryngotracheitis virus, Strain LT-IVAX (Modified live vaccine), Obtained from Poultry Health and Specialties, St. Cloud, MN	**Yes**
52026305							• Infectious Bursal Disease virus obtained from Solvay Animal Health	**Yes**
52026306							• Avian Infectious Bronchitis virus, Strain Beaudette 1B42, Obtained from Solvay Animal Health	**Yes**
52026307							• Bovine Viral Diarrhea virus as a surrogate virus for Human Hepatitis C virus	**Yes**

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil Load	Diluent	Organism(s)	Data support tested conditions?
52026308							• Porcine Respiratory & Reproductive Syndrome (PRRS) virus, NVSL Strain, Obtained from the University of Kentucky	**Yes**
52026309							• Pseudorabies virus, ATCC VR-135, Strain Aujeszky	**Yes**
52026310			Dilutable powder; 1:100 dilution (1%)				• New Castle Disease Virus / Strain: LaSota / Source: Charles River Laboratories	**Yes**
52026311			Dilutable powder; 1:200 and 1:400 dilutions				• African Swine Fever Virus, Strain Ba71V	**Yes**
52026312			Dilutable powder; 1:200 and 1:400 dilutions				• African Swine Fever Virus, Strain Georgia 2007	**Yes**

VI. LABEL COMMENTS

Label Date/Identification Number: 10/05/2022

1. The proposed label claims that the product, Neogen® Viroxide Super™, when diluted at 1.3 oz. per gallon of 400 ppm AOAC hard water, is an effective disinfectant with bactericidal activity against the following on visibly clean hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

Escherichia coli (ATCC 11229)	MRID 52026301
Salmonella enterica subspecies *enterica* serovar Typhimurium (ATCC 14028)	MRID 52026302

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Neogen® Viroxide Super™, when diluted at 1.3 oz. per gallon of 400 ppm AOAC hard water, is an effective disinfectant with virucidal activity against the following on visibly clean hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

Avian Influenza A (H5N1) virus, Strain VNHSN1 -PR8/CDC-RG, CDC #200671 9965	MRID 52026303
Infectious Laryngotracheitis virus, Strain LT-IVAX (Modified live vaccine)	MRID 52026304
Infectious Bursal Disease virus obtained from Solvay Animal Health	MRID 52026305
Avian Infectious Bronchitis virus, Strain Beaudette 1B42, Obtained from Solvay Animal Health	MRID 52026306
Bovine Viral Diarrhea virus as a surrogate virus for human Hepatitis C virus (NADL strain – ATCC VR-1422)	MRID 52026307
Porcine Respiratory & Reproductive Syndrome (PRRS) virus, NVSL Strain (Obtained from the University of Kentucky)	MRID 52026308
Pseudorabies virus, ATCC VR-135, Strain Aujeszky	MRID 52026309

These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product Neogen® Viroxide Super™, when diluted at 1:100 dilution in 400 ppm AOAC hard water, is an effective disinfectant with virucidal activity against the following on visibly clean hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

Newcastle Disease Virus / Strain: LaSota / Source: Charles River Laboratories	MRID 52026310

These claims are **acceptable** as they are supported by the submitted data.

4. The proposed label claims that the product, Neogen® Viroxide Super™, when diluted at 1:200 and 1:400 dilutions in 400 ppm AOAC hard water, is an effective disinfectant with virucidal activity against the following on visibly clean hard, non-porous surfaces in the presence of 5% organic soil for a 10-minute contact time:

African Swine Fever Virus, Strain Ba71V	MRID 52026311
African Swine Fever Virus, Strain Georgia 2007	MRID 52026311

5. Make the following changes to the proposed label:
   a. On page 3 under the directions for use, instruction #6 lists items that may not be hard, non-porous surfaces, such as halters and ropes, which is contradictory to instruction #5. Remove items that are not hard, non-porous materials.
   b. On pages 4-6 of the proposed label,
      i. Indicate that the surfaces to be disinfected should be hard, non-porous under the different sets of directions for use (i.e., Poultry Production and Ratite Production, Swine Production, etc.).
      ii. Under section: "To Clean Blankets, Saddle Pads and Rugs. Visible soil must be removed from surfaces prior to *disinfecting*". Clarify if this section is intended for cleaning or disinfecting surfaces. This product is intended to clean and disinfect hard non-porous surfaces, the surfaces mentioned in this section are porous surfaces. Data must be submitted for review in order to accept disinfecting claims on porous surfaces. Suggest revise language to say: "To Clean Blankets, Saddle Pads and Rugs. Visible soil must be removed from surfaces prior to **cleaning**".
   c. On pages 10-11 of the proposed label,
      i. Remove the word "destroys" when referencing microbes (e.g., "destroys bacteria and viruses…"). This word implies heightened efficacy of the product. This word may be replaced with "kills" or "disinfects" to accurately reflect testing.
      ii. Appropriately associate/link the asterisk (*) for viruses to the list of approved viruses (pages 6-7).
   d. On page 11, clarify language: "[Suitable to use on surfaces, equipment, vehicles, and water delivery system" to say: "[Suitable to use on **hard non-porous** surfaces, equipment, vehicles, and water delivery system".